K010382

MAR - 1 2001

510(K) SUMMARY

Submitter of 510 (K):

Sensidyne, Inc.
16333 Bay Vista Drive
Clearwater,
Fl. 33760

Tel: 727-530-3602 ext. 670
Fax: 727-539-0550
E-mail: gmason@sensidyne.com

Contact Person:

George Mason

Date of Summary:

January 29, 2001

Trade Name:

Sensidyne Inc.
16333 Bay Vista Drive
Clearwater,
Fl. 33760

Classification Name:

Oxygen Analyzer

Predicate Device:

Sensidyne Oxygen Analyzer

Device Description:

The 1000 Series Oxygen Analyzer is a compact oxygen measuring device which may be hand held, wall or table mounted. The instrument measures oxygen levels in a variety of medical applications. Each unit is serialized. The oxygen sensor is a standard galvanic cell manufactured by Ventrex Corp. under 510 (K) reference #K963415. A more complete Device Description is contained in: Section 9.

Comparison:

Oxygen Analyzer Comparison Chart:

Features	Sensidyne Analyzer	1000 Series Analyzer
Indications For Use	O_2 % Checking	O_2 % Checking
Sensor	Galvanic	Galvanic
Range	0-100%	0-100%
Display Resolution	0.1%	0.1%
Low Battery Indicator	Visual	Visual
Method Of Calibration	Software	Manual, Thumbwheel
Size	5.5"x3.6"x1.5"	4.6"x2.5"x1.4"
Power Source	2-AA Batteries	1-9Volt Battery
Weight	215 Grams	200 Grams
Cable Length	10 Ft.	10 Ft.

Intended Use:
The 1000 Series Oxygen Analyzer provides continuous/temporary measurement of oxygen mixtures in a wide variety of medical applications. The internally mounted sensor requires connection to a regulated gas source.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2001

Mr. George Mason
Sensidyne, Inc.
16333 Bay Vista Drive
Clearwater, FL 33760

Re: K010382
1000 Series Oxygen Analyzer
Regulatory Class: II (two)
Product Code: 73 CCL
Dated: February 6, 2001
Received: February 8, 2001

Dear Mr. Mason:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: Sensidyne Inc.

510(k) Number (if known): K010382

Device Name: 1000 Series Oxygen Analyzer

Indications For Use:

The 1000 Series Oxygen Analyzer provides continuous/temporary measurement of oxygen mixtures in a wide variety of medical device applications. The internally mounted sensor requires connection to a regulated gas source

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010382

Prescription Use HMP ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)